

Remarks

Claims 1, 3, 6 and 12-15 were pending. No claims are added or cancelled. Therefore, claims 1, 3, 6 and 12-15 are still pending.

Claims 1 and 6 have been amended to clarify the agent, by specifying a component structurally. To avoid confusion of the meaning of "HVJ-envelope" as HVJ-envelope proteins themselves, or as a vector prepared by using HVJ-envelope proteins and a foreign gene, the agent in claims 1 and 6 has been clarified to read as an "agent comprising a HVJ-envelope vector, wherein said HVJ-envelope vector comprises an isolated nucleic acid encoding a hepatocyte growth factor protein enclosed within an HVJ-envelope,".

Support for the amendments to claims 1 and 6 can be found throughout the specification, for example on page 4, lines 25-30; page 12, lines 13-18; page 12, lines 30 bridging through page 13, line 3; and page 18, lines 13-25. As described in the application, those skilled in the art will understand that reference to the "viral envelope vector" means an "HVJ-envelope vector as one of the representatives of the present application.

Claim 13 has been amended to properly recite the agent of claim 1, as kindly suggested by the Examiner.

No new matter has been added.

Applicants thank the Examiner for withdrawing many of the previous rejections.

Double Patenting Rejection

Claims 1, 3, 6, and 12-15 are rejected under the judicially created obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5 of U.S. Patent No. 6,936,594, in view of Hayashi *et al.* (*Gene Therapy* 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.* 28:130-7, 1987). Applicants disagree and request reconsideration.

The '594 patent and the present application are commonly owned.

It is asserted on page 4 of the Office action that, "The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from "HVJ-liposome", as recited in the claims of the cited patent.". Similar reasoning was used to reject the claims under 35 U.S.C. § 102(b).

As discussed below, claims 1 and 6 has been amended to be distinct from a liposome. Further, there is a significant difference between an HVJ-envelope and a liposome (for example see Barnes et al., page 130, left column, lines 1-4 of the body; cited in the Office action). The '594 patent neither discloses nor suggests the claims methods or agents, it cannot anticipate the present invention.

As acknowledged in the Office action, the previous obviousness-type double patenting rejection over the '594 patent has been withdrawn (page 3), and obviousness rejection under §103(a) over Morishita *et al.* (Australian Patent Appl. No. 200073148 B2) which corresponds to the '594 patent has also been withdrawn (pages 14-15).

Accordingly, Applicants assert that no terminal disclaimer is necessary, and request that the judicially created obviousness-type double patenting rejection be withdrawn.

35 U.S.C. §112, second paragraph

Claim 13 was rejected as being indefinite under 35 U.S.C. §112, second paragraph because there is insufficient antecedent basis for the limitation of "the method of claim 1".

As suggested by the Examiner, claim 13 has been amended to properly depend from claim 1 by reciting as "the agent of claim 1".

In view of this amendment, Applicants request that the 35 U.S.C. §112, second paragraph rejection be withdrawn.

35 U.S.C. §102(b)

Claims 1, 3, 6, and 12-15 are rejected under 35 U.S.C. §102(b) as anticipated by Morishita *et al.* (Australian Patent Appl. No. 200073148 B2, published on April 24, 2001, now

Patent No. 774990) as evidenced by Hayashi *et al.* (*Gene Therapy*, 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.*, 28:130-7, 1987). In addition, claims 1, 3, 6, and 12-15 are rejected as anticipated by Hayashi *et al.* as evidenced by Barnes *et al.*. Applicants disagree and request reconsideration.

It is asserted in the Office action that, "[the] "HVJ-envelope", as recited in the claims of the instant application, is not distinct from the "HVJ-liposome" taught by Morishita *et al.*". It is further asserted that, "Morishita *et al.* teaches an agent for cerebrovascular disorders comprising a hepatocyte growth factor gene . . . [and] an HVJ-liposome . . . the HVJ-liposome taught by Morishita and the HVJ-envelope of the instant application cannot be structurally distinguished (i.e., both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine and cholesterol.)."

Claims 1 and 6 have been amended to clarify the structure of the envelope. Specifically, the claims now expressly exclude a liposome. As Morishita *et al.* do not teach or suggest such an envelope structure, Morishita *et al.* do not anticipate the claims. Further, as described in Barnes *et al.* (page 130, left column, lines 1-4 of the body), the envelope of HVJ (Sendai virus) is composed of a lipid bilayer which contains, as asserted in the Office action, phosphatidylserine, phosphatidylcholine and cholesterol, but also two integral membrane glycoproteins (HN and F) that project from the viral surface, whereas a liposome does not have the glycoproteins such as HN and F proteins.

Similar to the anticipation rejection over Morishita *et al.*, it is asserted on page 11 of the Office action that "The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from the "HVJ-liposome" taught by Hayashi." As discussed above, the amendment of claims 1 and 6 clarifying the difference between an HVJ-envelope and a liposome (as evidenced by Barnes *et al.*, page 130, left column, lines 1-4 of the body) address this rejection.

The comment on page 10 and page 11-12 of the Office action "[u]se of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the

claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone", is not applicable to the amended claims. None of the references disclose the HVJ-envelope vector and the agent comprising the HVJ-envelope vector as defined by the claims of the present application. As both the vector and agent comprising the vector are novel, no limitation by a particular purpose of use is necessary. Accordingly, claim 1 has been amended to remove the phrase "for reducing an infarcted area of a cerebral infarction".

In view of the amendments to claims 1 and 6 and these arguments, Applicants request that the 35 U.S.C. § 102(b) rejections be withdrawn.

35 U.S.C. §102(e)

Claims 1, 3, 6, and 12-15 are rejected under 35 U.S.C. §102(e), as anticipated by Morishita *et al.* (US Patent No.6,936,594) as evidenced by Hayashi *et al.* (*Gene Therapy*, 8:1167-73, 2001) and Barnes *et al.* (*J. Lipid Res.*, 28:130-7, 1987). Applicants disagree and request reconsideration.

Similar to the above-anticipation rejection over Morishita *et al.* (Australian Patent Appl. No. 200073148 B2), it is asserted on page 13 of the Office action that, "The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from "HVJ-liposome", as recited in the claims of the cited patent." As discussed above, claims 1 and 6 have been amended to clarify the difference between an HVJ-envelope and liposome as evidenced by Barnes *et al.* (page 130, left column, lines 1-4 of the body).

The statement on page 14 of the Office action, "[u]se of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone", is not applicable for the amended claims. None of the references disclose the HVJ-envelope vector and the agent comprising the HVJ-envelope vector as defined by the claims of the present application. As both the vector and agent comprising the vector are novel, no limitation by a particular purpose of use is necessary. Accordingly, claim 1 has been amended to remove the phrase "for reducing an infarcted area of a cerebral infarction".

In view of the amendments to claims 1 and 6 and these arguments, Applicants request that the 35 U.S.C. § 102(e) rejections be withdrawn.

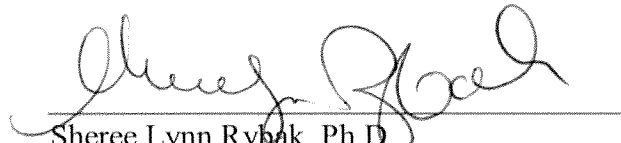
If any minor issues remain before a Notice of Allowance is issued, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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